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# **Recro Pharma Announces New IV Meloxicam Data Publication in the Journal Regional Anesthesia & Pain Medicine**

## **Publication Highlights a Pooled Analysis of IV Meloxicam’s Safety and Opioid-Reducing Effects Across Three Phase III and Four Phase II Studies**

MALVERN, Pa., Feb. 20, 2019 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (NASDAQ:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospitals and other acute care settings, today announced the publication of new intravenous (IV) meloxicam data. The article, titled “Meloxicam intravenous for the treatment of moderate to severe acute pain: a pooled analysis of safety and opioid-reducing effects,” was published online in *Regional Anesthesia & Pain Medicine*. A New Drug Application (NDA) for IV meloxicam is currently under review by the U.S. Food and Drug Administration (FDA) and the Company is currently awaiting its assigned PDUFA goal date of March 24, 2019.

“The pooled safety data from the Phase II/III clinical program shows that IV meloxicam was generally well-tolerated in patients with moderate to severe postoperative pain as indicated by a low incidence of treatment-emergent adverse events (TEAEs) that was comparable with placebo,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Recro Pharma. “Given the ongoing opioid epidemic, many expert healthcare organizations now recommend clinical strategies that utilize multimodal analgesia, which can include non-steroidal anti-inflammatory drugs (NSAIDs), to help reduce excessive opioid use. The opioid-reducing effects published today continue to support our belief that IV meloxicam has the potential to help physicians reduce the use of rescue opioids in the postoperative setting.”

The published data describe the pooled safety across a total of seven clinical studies (three Phase III and four Phase II), where IV meloxicam (5-15mg, 30mg or 60 mg) was evaluated in patients following several types of surgeries, including dental impaction surgery, open abdominal hysterectomy, abdominal laparoscopic surgery, bunionectomy, and abdominoplasty, among others. In this pooled analysis, IV meloxicam was generally well-tolerated, with the incidence of TEAEs occurring in a lower percentage of IV meloxicam-treated patients than in placebo-treated patients (47% versus 57%, respectively). The most commonly reported TEAEs across all treatment groups were nausea, headache, vomiting and dizziness. Notably, TEAE incidence was generally similar between the overall study populations and older patients (>65 years) with impaired renal function. There were no drug-related deaths for patients treated with IV meloxicam. Serious adverse events occurred at a lower frequency in the 30mg IV meloxicam treated group compared to the placebo group.

In the Phase II/III postsurgical study program where opioid rescue medication consumption was monitored, IV meloxicam was often associated with prolonged time to first rescue medication use and reduced rescue medication requirements. In the Phase III, randomized, double-blind, placebo-controlled trial evaluating IV meloxicam following major surgery (NCT02720692), IV meloxicam was associated with reduced opioid consumption. Mean opioid consumption in the overall population was significantly less in the IV meloxicam group compared with the placebo group in the hour 0–24, hour 0–48 and hour 0–72 intervals ( $p < 0.05$ ). Decreased opioid use among patients treated with IV meloxicam compared with placebo-treated subjects was observed across all subgroups (i.e., surgery type, risk group and demographic characteristics). In the IV meloxicam treatment group, decreased opioid use corresponded to fewer TEAEs commonly associated with opioid administration during the initial postoperative period. Additionally, in both the Phase II dental impaction and hysterectomy studies, the percentage of subjects using opioid medication after surgery was lower in the IV meloxicam (30mg) group compared with the placebo group (37% versus 95% and 58% versus 93%, respectively). Although a statistical evaluation was not conducted across the pooled studies, a trend indicating a decrease in adverse events commonly associated with opioid administration such as nausea, vomiting, constipation and pruritus was observed.

The full publication can be accessed [here](#).

### **About IV/IM Meloxicam**

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase (COX) and subsequent reduction in prostaglandin biosynthesis. IV meloxicam was designed using the NanoCrystal<sup>®</sup> platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal<sup>®</sup> is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

### **About Recro Pharma, Inc.**

Recro Pharma is a specialty pharmaceutical company that operates through two business divisions, an Acute Care, hospital product division and a revenue-generating contract development and manufacturing, or CDMO, division, located in Gainesville, GA. The Acute Care division is primarily focused on developing innovative products for the hospital and other acute care settings. The Company's lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled Phase III safety trial and four Phase II clinical efficacy trials, as well as other safety studies. Recro's Complete Response to the CRL for IV meloxicam was accepted for filing by the FDA in early October 2018 and assigned a PDUFA date of March 24, 2019. As injectable meloxicam is in the non-opioid class of drugs, if approved, the Company believes it has the potential to overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well as having no addictive potential while maintaining meaningful analgesic effects for relief of pain. The Company's CDMO division leverages its formulation expertise to develop and manufacture pharmaceutical products using its proprietary delivery technologies and other manufacturing services for commercial and development-stage partners who

commercialize or plan to commercialize these products. These collaborations can result in revenue streams including royalties, profit sharing, research and development and manufacturing fees, which support continued operations for its CDMO division, and it contributes non-dilutive funding for the development and pre-commercialization activities of its Acute Care division.

### **Cautionary Statement Regarding Forward Looking Statements**

This press release contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements reflect Recro's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "intend" and "expect" and similar expressions, as they relate to Recro or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Recro as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Recro's performance to differ materially from those expressed in, or implied by, these forward-looking statements. Recro assumes no obligation to update any such forward-looking statements. Factors that could cause Recro's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: the Company's ability to resolve the deficiencies identified by the FDA in the CRL for IV meloxicam; whether the FDA will approve the Company's amended NDA for IV meloxicam and, if approved, the labeling under any such approval; if the FDA does not approve the Company's amended NDA, the time frame otherwise associated with resolving the deficiencies identified by the FDA in the CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies; the Company's ability to successfully launch and commercialize IV meloxicam, if approved; the length, cost and uncertain results and timing of the Company's clinical trials, including the Company's Phase IIIb clinical trials and any additional clinical trials that the FDA may require in connection with IV meloxicam; the extent to which IV meloxicam, if approved, is accepted by the medical community, including physicians, patients, health care providers and hospital formularies; the availability of coverage and adequate and timely reimbursement for IV meloxicam, if approved; the Company's ability to raise future financing for continued product development, IV meloxicam commercialization and the payment of milestones; the Company's ability to achieve its financial goals, including financial guidance; the Company's ability to access funding and pay its debt under its credit agreement; regulatory developments in the United States and foreign countries; customer product performance and ordering patterns, the performance of third-party suppliers and manufacturers; the Company's ability to maintain relationships with CDMO commercial partners; and the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. In particular, there can be no assurance that the FDA will complete its review by the PDUFA goal date, that the FDA will not require changes or additional data with respect to the amended NDA or that the FDA will approve the amended NDA. The forward-looking statements in this press release should be considered together with the risks and uncertainties that may affect Recro's business and future results included in Recro's filings with the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

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